RESPONSE

I. Status of the Claims

Claim 2 has been cancelled entirely without prejudice and without disclaimer. Claims 5 and 7 have been amended for clarity. New claims 9-13 have been added to better and more clearly claim the present invention. As a result, claims 1 and 3-13 are pending in the present case. All pending claims are rejected under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph.

II. Support for the Claims

Claim 5 has been amended for clarity. This amendment to claim 5 finds support throughout the specification, claims and sequence listing as originally filed, with particular support being found in previous claim 5 and original claim 3.

Claim 7 has also been amended for clarity. This amendment to claim 7 finds support throughout the specification, claims and sequence listing as originally filed, with particular support being found in previous claim 7 and original claim 4.

New claim 9 has been added to more clearly claim aspects of the invention. Claim 9 finds support throughout the specification, claims and sequence listing as originally filed, with particular support being found in original claim 4 on which it depends and on original SEQ ID NO: 3.

New claim 10 has been added to more clearly claim aspects of the invention. Claim 10 finds support throughout the specification, claims and sequence listing as originally filed, with particular support being found in previously presented claim 5 on which it depends and on original SEQ ID NO: 1.

New claim 11 has been added to more clearly claim aspects of the invention. Claim 11 finds support throughout the specification, claims and sequence listing as originally filed, with particular support being found in previously presented claim 7 on which it depends and on original SEQ ID NO: 3.

New claim 12 has been added to more clearly claim aspects of the invention. Claim 12 finds support throughout the specification, claims and sequence listing as originally filed, with particular support being found in previously presented claim 6 on which it depends and on original SEQ ID NO:

1.

New claim 13 has been added to more clearly claim aspects of the invention. Claim 13 finds support throughout the specification, claims and sequence listing as originally filed, with particular support being found in previously presented claim 8 on which it depends and on original SEQ ID NO: 3.

As the amendments to claims 5 and 7 and new claim 9-13 are fully supported by the specification, sequence listing and claims as originally filed, they do not constitute new matter. Entry is therefore respectfully requested.

III. Rejection of Claims Under 35 U.S.C. § 101

The Final Action rejects the pending claims under 35 U.S.C. § 101, allegedly because the claimed invention lacks support by either a specific and substantial asserted utility or a well established utility. Applicants respectfully traverse.

The Final Action discounts many of the numerous utilities described in the specification for the sequences of the present invention based on the position that while credible, these utilities are not specific or substantial. While Applicants in no way agree with the Examiner's arguments, Applicants have chosen to expand on only a few of the asserted utilities presented in previous Responses, which are herein incorporated by reference, as only one is required.

Applicants respectfully submit that the legal test for utility involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. According to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on lack of utility (66 Federal Register 1098, January 5, 2001).

In *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

> At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (C.C.P.A. 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Even under the newly installed utility guidelines, Applicants note that MPEP 2107 (II)(B)(1) states:

> (1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. (MPEP 2107 (II)(B)(1))

Applicants would like to invite the Examiner's attention to the fact that a sequence sharing 99% identity at the amino acid level with the sequences of the present invention is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by third party scientists *wholly unaffiliated with Applicants* as G protein-coupled receptor 158 [*Homo sapiens*](GenBank accession number AAS18315, and IPI00257717 *Homo sapiens* (XM_166110) G PROTEIN-COUPLED RECEPTOR 158, information and alignment provided as **Exhibit A**, this evidence is being presented at this time because it entered the database in Feb 2004). The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given this GenBank annotation, there can be little question that those skilled in the art would clearly believe that Applicants' sequence is a human G protein-coupled receptor, as set forth in the specification as originally filed. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner's continued position indicating a need for examples or data is misplaced as it has long been established that "there is no statutory requirement for the disclosure of a specific example". *In re Gay*, 135 USPQ 311 (C.C.P.A. 1962) and that "an inventor is not required to understand the theory of how his invention works". *Micro Motion, Inc. v. Exac Corp.,* 16 USPQ2d 1001, 1013 (Cal. 1990). And in fact the biological function of the claimed invention has been disclosed, it is G protein-coupled receptor 158 and has all the functions of G protein-coupled receptor 158 that are know to those of skill in the art. Indeed, it is difficult to accept the given the propensity of knowledge surrounding G protein-coupled receptors, in published articles and books, issued patents and the like, that one of skill in the art would not know what to do with the claimed invention and would not readily recognize its utility. Absent any evidence of record that the described G protein-coupled receptor somehow fails to function as those of skill in the art would believe, the Examiner has failed to meet his/her burden of establishing that the Applicants' assertion of protein function is not credible. Accordingly, the Examiner is respectfully requested to either provide data that substantially and specifically refutes the Applicants' asserted function/utility, or withdraw the rejection.

Further, Applicants respectfully submit that the present situation parallels Example 10 of the PTO's Revised Interim Utility Guidelines Training Materials (pages 53-55), which establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112,

first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility, is not proper when there is no reason to doubt the asserted utility of a full length sequence (such as the presently claimed sequence) that has a similarity to a protein having a known function. The function of G protein-coupled receptors such as that of the present invention, are known to those of skill in the art. Thus the rejection of the presently claimed invention under a 35 U.S.C. § 101 and a 35 U.S.C. § 112 first paragraph utility rejection should not have been made and should thus be withdrawn.

As described extensively in previous responses G protein-coupled receptors have a number of substantial and credible utilities that are well recognized by those of skill in the art. As taught in the application and as well known to those of skill in the art, G protein coupled receptors play a critical role in, *intra alia*, signal transduction and cell activation. In fact, many oncogenes are linked to G protein-coupled receptors and G protein-coupled receptors. The present application describes a novel G protein-coupled receptor. Many pharmaceutical products currently being marketed by the entire industry target G protein-coupled receptors (Gurrath, 2001, Curr. Med. Chem. *8*:1257-1299, **Exhibit B**, described but not provided previously). Therefore, the identification of a new and novel human G protein-coupled receptor has great utility.

Although the above discussion is believed to be dispositive of the utility issue, Applicants reiterate that parts of the specification describe the use of sequences in a gene chip format to provide a high throughput analysis of the relevant cellular "transcriptome", including assessing temporal and tissue specific gene expression patterns, particularly using a high throughput "chip" format (specification at or about page 8, line 24 through page 10).

Evidence of the "real world" substantial utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies which have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, one such company, Rosetta Inpharmatics, was viewed to have such "real world" value that it was acquired by large pharmaceutical company, Merck & Co., for substantial sums of money (net equity value of the transaction was $620 million). The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well

established. Clearly, persons of skill in the art, as well as venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. Billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, *e.g.*, Venter *et al.*, 2001, Science *291*:1304, **Exhibit C**, described but not provided previously). The results have been a stunning success as the utility of human genomic data has been widely recognized as a great gift to humanity (see, *e.g.*, Jasny and Kennedy, 2001, Science *291*:1153, **Exhibit D**, described but not provided previously). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years). The sequences of the present invention have particularly specific utility in DNA gene chip based analysis as they have been identified to contain several coding region single nucleotide polymorphisms (cSNPs), thus increasing their utility in DNA gene chip based analysis.

DNA chips clearly have utility, as evidenced by hundreds of issued U.S. Patents, as exemplified by U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, 5,837,832, 6,156,501 and 6,261,776 (**Exhibits E-J**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy). Accordingly, the present sequence has a specific utility in such DNA chip applications. Clearly, compositions that enhance the utility of such DNA chips, like the present sequences, which encode human G protein- coupled receptor 158 and have a characterized tissue expression pattern, must have utility. The sequences of the present invention which encode human G protein- coupled receptor 158, provide specific markers for a human genome. Thus, those skilled in the art would instantly recognize that the sequences of the present invention would be an ideal, novel candidate for assessing gene expression using, for example, DNA chips, as the specification details. Accordingly, the present sequence has a specific utility in such DNA chip applications. Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequence encoding human G protein-coupled receptor 158, must also be useful.

The Examiner is further requested to reconsider that, given the huge expense of the drug discovery process, even negative information obtained using these specific markers of expression of human G protein-coupled receptor 158, provides great "real world" practical utility. Knowing that the

human G protein-coupled receptor gene is not expressed in medically relevant tissue provides an informative finding of great value to industry by allowing for the more efficient deployment of expensive drug discovery resources. Such practical considerations are equally applicable to the scientific community in general, in that time and resources are not wasted chasing what are essentially scientific dead-ends (from the perspective of medical relevance). Clearly, compositions that enhance the utility of DNA gene chips, such as the presently claimed sequences encoding human G protein-coupled receptor 158 must in themselves be useful. Moreover, the presently described human G protein-coupled receptor 158 sequences provide uniquely specific sequence resources for identifying and quantifying full length transcripts that were encoded by the corresponding human genomic locus. Accordingly, there can be no question that the described sequences provide an exquisitely specific utility for analyzing gene expression. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Further evidence of utility of the presently claimed polynucleotide, although only one is needed to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), is the specific utility the present nucleotide sequence has in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions as described in the specification.

Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the polynucleotide that encodes human G protein-coupled receptor 158, a utility not shared by virtually any other nucleic acid sequence. In fact, it is this specificity that makes this particular sequence so useful. Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human genome, such as the present nucleic acid sequence.

The Final Action discounts Appellants' assertion regarding the use of the presently claimed polynucleotides for gene mapping and determining chromosome structure again based on the position

that such a use would allegedly be generic and therefore fail to represent a specific and substantial utility. However, as only a minor percentage of the genome actually encodes exons, which in turn encode amino acid sequences, the presently claimed polynucleotide sequence provides biologically validated empirical data (*e.g.*, showing which sequences are transcribed, spliced, and polyadenylated) that *specifically* defines that portion of the corresponding genomic locus that actually encodes exon sequence. Equally significant is that the claimed polynucleotide sequence defines how the encoded exons are actually spliced together to produce an active transcript (*i.e.*, the described sequences are useful for functionally defining exon splice-junctions). The Applicants respectfully submit that the practical scientific value of expressed, spliced, and polyadenylated mRNA sequences is readily apparent to those skilled in the relevant biological and biochemical arts. For further evidence supporting the Applicants' position, the Board is requested to review, for example, section 3 of Venter *et al.* (*supra at* pp. 1317-1321, including Fig. 11 at pp.1324-1325), which demonstrates the significance of expressed sequence information in the structural analysis of genomic data. The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome essentially as described in the Venter *et al.* article.

Evidence of utility of the presently claimed polynucleotide, is the specific utility that the present nucleotide sequence has in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions as described in the specification. As evidence supporting Applicants assertions of the specific utility of the sequences of the present invention in localizing the specific region of the human chromosome and identification of functionally active intron/exon splice junctions was the information provided as Exhibit B of Applicant's Earlier Response (paper no. 18). This evidence resulted from the overlaying the sequence of SEQ ID NO:1 of the present invention and the identified human genomic sequence. By doing this, one is able to identify the portions of the genome that encode the present invention. If these regions of the genome are non-contiguous, this is indicative of individual exons. The results of such an analysis indicates that the sequence of the present invention is encoded by 11 exons spread non-contiguously along a region of human chromosome 10. Thus clearly one would not simply be able to identify the 11 or more protein encoding exons that make up the sequence of the present intention from within the large genomic sequence. Nor, would one be able to accurately map the protein encoding regions identified

specifically by the sequences of the present invention without knowing exactly what those specific sequences were. Additionally, it should be noted that human G protein-coupled receptor 158 gene is now recognized to map to the same region of human chromosome 10 (10p12.31). This further supports Applicant's position that the sequences of the present invention encode human G protein-coupled receptor 158.

In addition, Applicants note that among other things the mapping of the relatively few expressed human genes to a particular chromosome has long been a recognized method of identifying a genes associated with particular diseases. Furthermore, the mapping of the human chromosome is a project of such widely recognized importance by those of skill in the art and even lay people, that both the US government and private corporations have dedicated millions of dollars to such a project. One is thus forced to ask, if the mapping of human chromosomes is a throw away utility then why has the US government spent so many taxpayer dollars on this project? The Final Action's repeated position that this utility, like the use of these specific sequences on DNA chips is that since other molecules can be used to map the human chromosome or on DNA chips, these utilities are not specific or substantial.

The assumption that since any sequence that encodes a functional human gene can be used renders such utilities generic and therefore without substantial and specific utility may represent a confusion between the requirement for a specific utility, which is the proper standard for utility under 35 U.S.C. § 101, with a requirement for a unique utility. Relevant case law cited by Applicants makes it abundantly clear that the presence of other human gene sequences does **not** mean that the present sequences lack a specific utility, for each represent a specific gene and its product. As clearly stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Importantly, the holding in the *Carl Zeiss* case is mandatory legal authority that essentially controls the outcome of the present appeal. This case, and particularly the cited quote, directly rebuts such argument. Furthermore, the requirement for a unique utility is clearly not the standard adopted by the

Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer and bacterial or viral infections, just to name a few particular examples, because examples of each of these have already been described and patented. All batteries have the exact same utility - specifically, to provide power. All automobile tires have the exact same utility - specifically, for use on automobiles. All golf balls and golf clubs have the exact same utility - specifically, use in the game of golf. All cancer treatments have the exact same utility - specifically, to treat cancer. All anti-infectious agents have the exact same broader utility - specifically, to treat infections. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Furthermore, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

It has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974; "*Langer*"); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). As clearly set forth in *Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Finally, Applicant's recognize fully and accept the Examiner's position with regard to USPTO

policy, the fact that all patent applications are examined on their own merits and that the prosecution of one patent does not effect the prosecution of another patent (*In re Wertheim,* 541 F.2d 257, 264, 191 USPQ 90, 97 ((CCPA 1976)). However, Applicants also note that the issue at hand in one of whether the fact that patents have issued recognizing the utility of a class of molecules, confers a statutory precedent of patentability to a broad class of compositions. Thus, there remains a lingering issue regarding due process and equitable treatment under the law. While Applicants are well aware of the new Utility Guidelines set forth by the USPTO, Applicants respectfully point out that the current rules and regulations regarding the examination of patent applications are and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Applicants are unaware of any significant recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines. As examples of such issued U.S. Patents, the Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claims short polynucleotides; **Exhibits K-M**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy), and recently issued U.S. Patent No. 6,340,583 (which includes no working examples; **Exhibit N**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy), none of which contain examples of the "real-world" utilities that the Examiner appears to desire. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section IV, below), Applicants submit that the present polynucleotides must also meet the requirements of 35 U.S.C. § 101.

Furthermore with specific applicability to the present case, regarding the patentablility of G protein-coupled receptors, is issued issued U.S. Patent 6,043,052 (**Exhibit O**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy) in which methods similar to those of the present invention were used to identify the G protein-coupled receptor. Issued U.S. Patents are presumed to be valid and to meet the requirements of 35 U.S.C. §§ 101, 102,

103 and 112, specifically, that they have utility, are novel, non-obvious, are enabled, meet the written description requirements and particularly point out and distinctly claim the invention. Therefore, the Applicants' assertion that the described G protein-coupled receptor is in fact a G protein-coupled receptor is supported by issued U.S. Patent 6,043,052, as well as the plethora of other G protein-coupled receptor patents that the office has issued. For example, the specific and substantial utility of human G protein-coupled receptors is evidenced by the fact that they are the subject of the above mentioned U.S. Patent No. 6,043,052 which discloses polynucleotides encoding a novel G protein-coupled receptor and U.S. Patent Nos. 5,891,646 and 6,110,693 (**Exhibits P and Q**; copies of issued U.S. Patents not provided pursuant to current United States Patent and Trademark Office policy), both of which disclose and claim methods for detecting G protein-coupled receptor activity *in vivo* and *in vitro*, methods for assaying G protein-coupled receptor activity, and methods of screening for G protein-coupled receptor ligands, G protein-coupled receptor kinase activity, components that interact with G protein-coupled receptor regulatory processes and constructs useful in such methods. The issuance of these U.S. patents clearly indicates that G protein-coupled receptor polynucleotides have been recognized to have utility and that such utilities were sufficiently specific and substantial to warrant the issuance of U.S. patents directed to methods used to identify and characterize G protein-coupled receptors. The teachings of these patentable disclosures are directly applicable to the present invention (G protein-coupled receptor polynucleotides) and are evidence that those skilled in the art recognize the specific and substantial utility of G protein-coupled receptors. In light of the issuance of U.S. Patent No. 6,043,052 on polynucleotides encoding a novel G protein-coupled receptor, Applicants respectfully submit that the present application, which also describes polynucleotides encoding a human G protein-coupled receptor (GPR158), describes an invention with specific and substantial utility fully compliant with 35 U.S.C. § 101.

While Applicants agree that each application is examined on its own merits, Applicants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. Thus, holding Appellants invention to a <u>different</u> standard of utility appears inconsistent and inequitable, such a

judgement being arbitrary and capricious, a violation of due process and equal protection under the law and cannot be maintained.

In light of the evidence presented herewith and for the many compelling reasons described in previous Responses, it is clear that the present invention clearly has utilities that are specific, substantial and credible. Therefore, Applicants submit that the rejection of the pending claims under 35 U.S.C. § 101 has been avoided and respectfully request withdrawal of the pending rejection of claims under 35 U.S.C. § 101.

IV. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Final Action next rejects the pending claims under 35 U.S.C. § 112, first paragraph, since the claimed invention is not supported by either a specific substantial and credible utility, or a well established utility, one skilled in the art clearly would not know how to use the claimed invention.

Applicants respectfully submit that the pending claims have been shown to have "a specific, substantial, and credible utility", as detailed in the section above. Therefore, one skilled in the art would clearly know how to use the claimed invention and Applicants therefore request that the rejection of claims. Therefore, Applicants submit that as the presently claimed sequence molecules have been shown to have a substantial, specific, credible and well-established utility, and thus the rejection of the claims under 35 U.S.C. § 112, first paragraph has been avoided. Thus, Applicants respectfully request that the rejection be withdrawn.

V. Conclusion

The present document is a full and complete response to the Final Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Li have any questions or

comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

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